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UNITED STATES DISTRICT COURT

## DISTRICT OF ARIZONA

# IN RE: Bard IVC Filters Products Liability Litigation

No. 2:15-MD-02641-DGC

DORIS JONES and ALFRED JONES, a married couple,

### **Plaintiffs.**

V.

C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation,

## Defendants.

Case No: 2:16-cv-00782

**PLAINTIFFS' CONTROVERTING  
STATEMENT OF FACTS TO  
DEFENDANTS' SEPARATE  
STATEMENT OF FACTS IN  
SUPPORT OF MOTION FOR  
SUMMARY JUDGMENT AS TO  
PLAINTIFFS DORIS AND ALFRED  
JONES'S CLAIMS**

(Assigned to the Honorable David G.  
Campbell)

In response to each of the paragraphs in Defendants' Separate Statement of Facts ("Bard SOF") [Doc. 7352], Plaintiffs Doris and Alfred Jones respond as follows:

1. Plaintiff Doris Jones received a Bard Eclipse® Filter (the “Filter”)

(Ex. A. Plaintiff Fact Sheet of Plaintiff Doris Jones

(hereinafter “PFS”), at §§ II.2(a), II.3; Ex. B, Selected Plaintiff Medical Records, at JONESD\_MUMC\_MDR01287-88).

**Plaintiffs' Response:** Admit.

2. The Filter is not sold directly to patients. (Ex. C, Eclipse Filter Instructions for Use (the “Eclipse IFU”) at page 1.)

Plaintiffs' Response: Disputed. Defendants' exhibit does not support their assertion of fact as required by Rule 56(c). The Eclipse IFU cited by

1 Defendants states, “Caution: Federal (U.S.A.) law restricts this device to sale by or  
2 on the order of a physician.” The Eclipse IFU does not support Defendants’  
3 contention that the Filter is not (or cannot be) sold directly to patients. Further, the  
4 Plaintiff was billed for her Eclipse IFU. See JONES\_MUMC\_BIL00064, attached as  
5 Exhibit 1. Defendants’ statement is silent as to the identity of the seller at issue.

6 3. In 2006, before the Filter was implanted, Mrs. Jones experienced [REDACTED]  
7 [REDACTED]  
8 [REDACTED]. (Ex. B, Selected Plaintiff  
9 Medical Records, at JONESD\_UFHJ\_MDR00266).

10 **Plaintiffs’ Response:** Admit

11 4. In 2009, Mrs. Jones was [REDACTED]  
12 [REDACTED] (*Id.* at JONESD\_MUMC\_MDR01548-1549).

13 **Plaintiffs’ Response:** Admit [REDACTED]  
14 [REDACTED].

15 5. Despite her doctors’ earlier advice, [REDACTED]  
16 [REDACTED]  
17 [REDACTED] (*Id.* at JONESD\_MUMC\_MDR00452-456).

18 **Plaintiffs’ Response:** Dispute [REDACTED]

19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]. *Id.* Plaintiffs admit that Doris Jones [REDACTED]  
24 [REDACTED].

25 6. She had also previously been told [REDACTED]  
26 [REDACTED] (*Id.* at JONESD\_MUMC\_MDR00723).

27 **Plaintiffs’ Response:** Dispute [REDACTED] Mrs.  
28 Jones was not able to obtain treatment or medical care of any kind due to her

1 financial situation and lack of health insurance, not because of any refusal to seek  
2 care. Transcript of deposition of Shanice Matthews, dated Aug. 7, 2017, attached as  
3 Ex. 2, at 15:18-23; Transcript of deposition of Sharese May, dated Aug. 7, 2017,  
4 attached as Ex. 3, at 42:4-16. The record Bard cites is not competent evidence of this  
5 alleged fact.<sup>1</sup>

6 7. In August 2010, Mrs. Jones [REDACTED]  
7 [REDACTED]  
8 [REDACTED] (*Id.* at  
9 JONESD\_MUMC\_MDR01287-88).

10 **Plaintiffs' Response:** Disputed [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]

14 8. Mrs. Jones' implanting physician, Dr. Anthony Avino, [REDACTED]  
15 [REDACTED]  
16 [REDACTED]  
17 [REDACTED] (Ex. D,  
18 March 23, 2017, Deposition Transcript of Anthony Avino, M.D. ("Avino Dep. Tr.") at  
19 110:22 to 113:25.)

20 **Plaintiffs' Response:** Objection; this statement mischaracterizes Dr.  
21 Avino's testimony. Subject to that objection, Plaintiffs dispute this alleged fact.  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 [REDACTED]

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26 <sup>1</sup> Plaintiffs admit that the referenced documents contains statements attributed to Doris  
27 Jones, but there is no competent medical evidence this actually happened. But given the  
28 alleged fact's utter irrelevance to any argument on summary judgment by either party,  
Plaintiffs will not burden the Court with additional filings.

1 [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 9. [REDACTED]  
5 [REDACTED] (Ex. B, Selected Plaintiff Medical Records, at  
6 JONESD\_MUMC\_MDR01287-88).

7 **Plaintiffs' Response:** Dispute this is an accurate quote. The relied-upon  
8 document states Mrs. Jones [REDACTED]  
9 [REDACTED] See Bard SOF Ex. B  
10 at JONESD\_UFHJ\_MDR01287 (emphasis supplied).

11 10. Dr. Avino testified that [REDACTED]  
12 [REDACTED]  
13 (*Id.* at ¶ #). [REDACTED] (Ex. D, Avino Dep. Tr. at 54:14 to  
14 55:8.)

15 **Plaintiffs' Response:** Objection; this statement mischaracterizes Dr.  
16 Avino's testimony. Subject to that objection, Plaintiffs dispute this alleged fact. Dr.  
17 Avino testified that he did not recall such a discussion with Mrs. Jones. [REDACTED]  
18 [REDACTED]  
19 [REDACTED]  
20 [REDACTED]  
21 [REDACTED]  
22 [REDACTED]

23 Bard SOF Ex. D at 54:14-23. He further testified.

24 [REDACTED]  
25 [REDACTED]  
26 [REDACTED]  
27 *Id.* at 55:9-15. Additionally, it was Alfred Jones—not Doris Jones—who spoke with  
28 Dr. Avino, [REDACTED]

1 [REDACTED] Transcript of deposition of Doris  
 2 Jones, dated Feb. 3, 2017, attached as Ex. 4, at 33. Alfred Jones recalls the  
 3 conversation with Dr. Avino and its contents. Transcript of deposition of Alfred  
 4 Jones, dated Feb. 3, 2017, attached as Ex. 5, at 23-25.

5 11. [REDACTED] (Ex. B, Selected Plaintiff Medical  
 6 Records, at JONESD\_MUMC\_MDR01287-88).

7 **Plaintiffs' Response:** Admit.

8 12. Dr. Avino testified that he does not recall ever reading the IFU. (Ex. D,  
 9 Avino Dep. Tr. at 47:21-23)

10 **Plaintiffs' Response:** Objection; mischaracterizes Dr. Avino's testimony.  
 11 Subject to that objection, Plaintiffs dispute this alleged fact. Dr. Avino testified while  
 12 he didn't "read them on every package, because they're the same from the same  
 13 device," he did read and was familiar with the IFUs for Bard's IVC filters. Bard  
 14 SOF Ex. D at 47:11-20. He could not specifically recall whether he had read the IFU  
 15 for the Eclipse IVC filter. *Id.* at 47:21-23. Moreover, the warnings and potential  
 16 complications in the IFUs for the Eclipse and its two immediately preceding devices  
 17 (G2X and G2) are identical with respect to the issues here. See Plaintiffs' Omnibus  
 18 Statement of Facts, filed contemporaneously, ¶¶ 278-282.

19 13. Dr. Avino was "generally familiar with IVC filter IFUs, if they warn of  
 20 things like fractures, migration, perforation, tilt; complications like that," and began  
 21 implanting IVC filters during his residency, 20 years before he implanted Mrs. Jones'  
 22 filter. (*Id.* at 8:16-23; 29:15-25; 48:2-7.)

23 **Plaintiffs' Response:** Admit except to the extent Bard is suggesting this is  
 24 the limit of Dr. Avino's familiarity with IFUs for IVC filters. See Response to Bard  
 25 SOF ¶ 12, above.

26 14. The Eclipse IFU applicable in August 2010 (when Plaintiff received her  
 27 Filter) included the following warnings:

- 28 • Under the bolded heading "Warnings" the Eclipse® IFU reads as follows:

- 1           •     Filter fractures are a known complication of vena cava filters. There  
 2           have been some reports of serious pulmonary and cardiac  
 3           complications with vena cava filters requiring the retrieval of the  
 4           fragment utilizing endovascular and/or surgical techniques.

5           (Ex. C, Eclipse IFU at p. 2.)

6           **Plaintiffs' Response:**     Admit that the quoted language appears in the  
 7           Eclipse IFU under the heading warnings. Bard fails to indicate that the quoted  
 8           language is listed as item 11 of 14. See Bard SOF Ex. C at 2.

9           15.    This warning is repeated under the bolded heading “**Potential**  
 10          **Complications**”, which also adds that:

11          \* \* \*

12          **All of the above complications have been associated with serious adverse**  
 13          **events such as medical intervention and/or death. There have been reports of**  
 14          **complications including death, associated with the use of vena cava filters in**  
 15          **morbidly obese patients. The risk/benefit ratio of any of these complications**  
 16          **should be weighed against the inherent risk/benefit ration for a patient who is**  
 17          **at risk of pulmonary embolism without intervention.**

18          (*Id.* at pp. 2-3.)

19          **Plaintiffs' Response:**     Disputed. Bard has not fully and correctly quoted  
 20          the document. The correct quote begins: “All of the above complications may be  
 21          associated with serious adverse events . . .” See Bard SOF Ex. C at 3 (emphasis  
 22          added). Otherwise, Plaintiffs admit that the quoted language (except for a typo in  
 23          the word “ratio”) appears in the Eclipse IFU under the heading Potential  
 24          Complications.

25          16.    The “Clinical Experience” section notes the number of fracture observed  
 26          during the clinical study of one hundred patients. (*Id.* at p. 4.)

27          **Plaintiffs' Response:**     Admit

28          17.    In April 2015, [REDACTED]

29          [REDACTED]  
 30          [REDACTED] (Ex. B, Selected  
 31          Plaintiff Medical Records, at JONESD\_MUMC\_MDR00007-00011.)

1 **Plaintiffs' Response:** Admit [REDACTED]  
2 [REDACTED]  
3 [REDACTED] Plaintiffs dispute [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]  
7 [REDACTED] Bard SOF Ex. B at JONESD\_MUMC\_MDR00007 (emphasis added).  
8 18. [REDACTED]  
9 [REDACTED] (*Id.* at JONESD\_MUMC\_MDR00114-115.)  
10 **Plaintiffs' Response:** Admit [REDACTED]  
11 [REDACTED]  
12 [REDACTED]  
13 [REDACTED]  
14 19. [REDACTED]  
15 [REDACTED] (*Id.*; *Id.* at JONESD\_MUMC\_MDR00065.)  
16 **Plaintiffs' Response:** Disputed. [REDACTED]  
17 [REDACTED]  
18 [REDACTED] Bard  
19 SOF Ex. B at JONESD\_MUMC\_MDR00005. Additionally, the full quote of the  
20 record on which Bard relies reads as follows:  
21 [REDACTED]  
22 [REDACTED]  
23 [REDACTED]  
24 [REDACTED]  
25 *Id.* at JONESD\_MUMC\_MDR00065. It is not clear what the doctor meant by [REDACTED]  
26 [REDACTED]  
27 20. [REDACTED] (*Id.*  
28 at JONESD\_MUMC\_MDR00004-6).

1           Plaintiffs' Response:      Disputed. [REDACTED]  
2 [REDACTED]  
3 [REDACTED]  
4 [REDACTED]  
5 [REDACTED]  
6 [REDACTED]

7           21. Plaintiff's expert, Dr. Muehrcke, acknowledges that all IVC filters are  
8 known to have potential complications, including filter fracture, migration, tilt, and  
9 perforation. (Ex. E, July 24, 2017 Dr. Derek Muehrcke Deposition Transcript ("Muehrcke  
10 Dep. Tr."), at 55-22 to 57:9.)

11           Plaintiffs' Response:      Admit.

12           22. The plaintiffs' engineering expert testified that he is not aware of any IVC  
13 filter that has been developed that is complication free, (Ex. F, July 19, 2016 Dr. Robert  
14 McMeeking Deposition Transcript, at 133:19 to 134:19), nor is he aware of any  
15 implantable medical device that is one hundred percent complication free. (Ex. G, April  
16 22, 2014 Dr. Robert McMeeking Deposition Transcript, at 149:9-13).

17           Plaintiffs' Response:      **Objection; the questioner failed to establish**  
18 **adequate foundation for the testimony. Subject to that objection, disputed. Bard's**  
19 **alleged fact misstates Dr. McMeeking's testimony. Dr. McMeeking testified that it**  
20 **was possible for an IVC filter to be complication-free. Bard SOF Ex. F at 134:3-7.**  
21 **Additionally, he never testified that he was unaware of a complication-free device;**  
22 **rather, he testified that he lacked the data:**

23           **Q: And nobody has created an IVC filter that is complication free, have**  
24 **they? No company?**  
[Objections]

25           **A: I'm not sure. I don't – I don't have the data.**

26           *Id.* at 134:15-19.

27           23. As the plaintiffs' experts recognize, "[e]very filter can have a complication;"  
28 therefore, it would be "unrealistic" for a physician implanting a Bard IVC filter to expect

1 that the filter would never migrate, tilt, perforate, or fracture. (Ex. E, Muehrcke Dep. Tr.  
2 at 102:16 to 103:2).

**Plaintiffs' Response:** Disputed. Bard has failed to establish that this alleged position is held by multiple of “plaintiffs’ experts.” Bard cites testimony from a single expert. In response to the question of whether he believed that “a physician implanting a Bard filter has an expectation that under no circumstances, in no scenario, no matter what happens, that filter will not migrate,” Dr. Muehrcke testified “that’s an unrealistic expectation.” Dr. Muehrcke was then asked “And the same would be true as to tilt, perforation, or fracture?” He answered “Every filter can have a complication.” Bard SOF Ex. E at 102:16-103:2.

11       24. The Filter was cleared by the FDA for retrievable use on January 14, 2010,  
12 through the 510(k) process outlined in the Food, Drug, and Cosmetic Act. (Ex. H, August  
13 29, 2005 FDA Clearance Letter<sup>2</sup>).

14        **Plaintiffs' Response:**      Admit. [Plaintiffs note that the reference appears to  
15 include a typo as to the date of the FDA Clearance letter.]

16 || RESPECTFULLY SUBMITTED this 2nd day of October 2017.

GALLAGHER & KENNEDY, P.A.

By:/s/ *Paul L. Stoller*

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<sup>28</sup> Available at [https://www.accessdata.fda.gov/cdrh\\_docs/pdf9/K093659.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf9/K093659.pdf), last accessed August 25, 2017.

## **CERTIFICATE OF SERVICE**

I hereby certify that on this 2nd day of October 2017, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Deborah Yanazzo

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